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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/576,485 | 04/21/2006 | Huang-Ping Wu | BYD02_010_US | 5411 |
| 66140 7590 08/03/2009 BLANCHARD & ASSOCIATES 566 WEST ADAMS STREET SUITE 600 CHICAGO, IL 60661 | | | EXAMINER SALZMAN, KOURTNEY R | |
| | | | ART UNIT 1795 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|----------------------------------|--|
| Office Action Summary | Application No. 10/576,485 | Applicant(s) WU ET AL. | |
| | Examiner KOURTNEY R. SALZMAN | Art Unit 1795 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,13-17,22,26,30,31,33,37,38,45,61,65 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,13-17,22,26,30,31,33,37,38,45,61,65,68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>May 19, 2006, October 24, 2007, February 19, 2009 and June 10, 2009</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. This is the first office action on the merits for application 10/576,485 filed 4/21/2006. This application is the 371 national phase filing of PCT/US04/35286, which claims priority to provisional application 60/513,817 filed October 24, 2003.
2. The preliminary amendment filed with the application on 4/21/2006 has been entered. This amendment cancels claims 3-5, 8-12, 18-21, 23-25, 27-29, 32, 34-36, 39-44, 46-59, 62-64, 66, 67 and 69-73.
3. Claims 1, 2, 6, 7, 13-17, 22, 26, 30, 31, 33, 37, 38, 45, 61, 65 and 68 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 13, 22, 26, 30, 31, 37, 38, 45, 61, 65 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by WINARTA et al (US 6,287,451 B1).

Regarding claim 1, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and electroactive organic molecule (c. 10, l. 49-52), a second electrode (R) and a second reagent layer comprising the pieces as described in the final limitation of the claim (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal

complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7.

Regarding claim 2, the reagent present on the electrodes is different as the first reagent mixture comprises an enzyme while the second does not, as described in column 10, 49-52 (the first reagent layer) and in column 10, lines 42-44 (the second reagent layer).

Regarding claim 13, WINARTA et al teaches ferricyanide to be present in the second reagent layer as the first soluble redox species in column 10, line 46.

Regarding claim 22, figure 2 of WINARTA et al shows piece 50 to function as lid which covers at least in part, the reagent layers, as required in the specification of the instant application, in paragraph 40 of the PG PUB.

Regarding claim 26, a third electrode is shown in to be present in figure 2 as W1. The reagent layer present is described in column 10, lines 41-44. The redox species is ferricyanide, as described in the second reagent mix.

Regarding claim 30, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and electroactive organic molecule (c. 10, l. 49-52), a second electrode (R) and a

Art Unit: 1795

second reagent layer comprising the pieces as described in the final limitation of the claim (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex which is a reducible species. This is a valid material for the organotransition component as it is listed in the instant application on page 7. The oxidoreductase is listed in column 10, lines 52-53 to be glucose oxidase.

Regarding claim 31, the reagent present on the electrodes is different as the first reagent mixture comprises an enzyme while the second does not, as described in column 10, 49-52 (the first reagent layer) and in column 10, lines 42-44 (the second reagent layer).

Regarding claim 37, WINARTA et al teaches, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and electroactive organic molecule (c. 10, l. 49-52), a second electrode (R) and a second reagent layer comprising the pieces as described in the final limitation of the claim (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. Areas 22, 24 and 26, or the electrical material comprising the electrodes is deposited onto the base, as described in column 7, lines 54-56. WINARTA et al teaches the dispensing of the reagents into the electrode areas in column 10, lines 41-42 and 49.

Art Unit: 1795

Regarding claim 38, the enzyme of W2, or the first reagent area, is stated to be glucose oxidase in column 10, lines 52-53.

Regarding claim 45, figure 2 of WINARTA et al shows piece 50 to function as lid which covers, at least in part, the reagent layers and electrodes.

Regarding claim 61, WINARTA et al discloses starting a reading by applying a blood sample to the strip in column 13, line 66-column 14, line 1. The sensor strip comprises, as shown in figure 2, a base (20), a first electrode (W2), a first reagent layer comprising an oxidoreductase and electroactive organic molecule (c. 10, l. 49-52), a second electrode (R) and a second reagent layer comprising the pieces as described in the final limitation of the claim (c. 10, l. 41-43), wherein ferricyanide is the organotransition metal complex. This is a valid material for the organotransition component as it is listed in the instant application on page 7. WINARTA et al teaches the application of potential, reading the current and correlating to concentrations in column 11, lines 59-66. Moreover, these are standard operating steps for electrochemical gas sensors which obtain readings on concentration.

Regarding claim 65, the enzyme of W2, or the first reagent area, is stated to be glucose oxidase in column 10, lines 52-53.

Art Unit: 1795

Regarding claim 68, WINARTA teaches the use of the glucose oxidase for making the sensor operate as a glucose sensor in column 9, lines 21-23.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1795

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA et al (US 6,287,451), in view of TANIKE et al (US PG PUB 2001/0006149).

WINARTA et al teaches the limitations of claims 1 and 2, but fails to explicitly teach the existence of a second redox species and the molar ratio of the first and second redox species.

TANIKE et al teaches in paragraph 48 for the first soluble redox species, ferricyanide to be present in a reagent layer, then the second species ferrocyanide to form when it reacts with the enzyme glucose oxidase. This would allow both species to be present in the operation of the sensor of WINARTA et al (even if not explicitly described therein, this reaction is standard in the electrochemical sensors of the same design) and TANIKE et al.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to cause both the ferrocyanide and ferricyanide species to be present in the sensor, as in TANIKE et al, in the sensor of WINARTA et al because it is the natural reaction when the mediator (ferricyanide) is combined with the glucose enzyme, as described in TANIKE et al. Regarding the molar ratios of claims 6 and 7, it would have been obvious for there to be an excess (or more than 1:1 ratio of the first soluble redox species (ferricyanide) to the second redox species (ferrocyanide, produced during the reaction) because if an excess is not present the reaction with the enzyme cannot proceed, causing an inaccurate reading in

Art Unit: 1795

the sensor itself. The first redox species would be the limiting agent, causing errors in the sensor concentration readings.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA et al (US 6,287,451), in view of MORRIS et al (Morris, N. A., M. F. Cardosi, B. J. Birch, and A. P. Turner. "An Electrochemical Capillary Fill Device for the Analysis of Glucose Incorporating Glucose oxidase and Ruthenium (III) Hexamine as Mediator." *Electroanalysis* 4.1 (1992): 1-9.).

WINARTA et al teaches all the limitations of claim 1, including the use of ferricyanide as the first soluble redox species. WINARTA et al fails to disclose ruthenium (II) hexamine or ruthenium (III) hexamine as the first soluble redox species.

MORRIS et al teaches a glucose sensor incorporating glucose oxidase with the use of ruthenium (III) hexamine as the mediator of choice in the abstract.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to utilize the ruthenium (III) hexamine mediator, as in MORRIS et al, as the mediator of WINARTA et al, because the use of a positively charged mediator (ruthenium (III) hexamine) improves the kinetics of the reaction over the use of negatively charged mediator such as ferricyanide, as stated by MORRIS et al on page 7. Moreover, it would have been obvious to substitute one known

Art Unit: 1795

mediator for another known mediator for the same result of electroactivity and electron-transfer.

11. Claims 15-17 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WINARTA et al (US 6,287,451), in view of BLOCZYNSKI et al (US 5,520,786).

WINARTA et al teaches all the limitations of claims 1 and 30, as discussed above including the use of ferricyanide as the electroactive organic molecule, but fails to detail the use of the materials disclosed in the above stated claims. While glucose oxidase is disclosed in the example, WINARTA et al discloses the use of any enzyme and mediator combination which work together as disclosed in column 8, lines 43-52.

BLOCZYNSKI et al teaches glucose sensor comprising the mediators 3-phenylimino-3H-phenothiazine or 3-phenylimino-3H-phenoxazine in the abstract.

At the time of the invention, it would have been obvious to utilize 3-phenylimino-3H-phenoxazine or 3-phenylimino-3H-phenothiazine, as in BLOCZYNSKI et al, for the ferricyanide mediator of WINARTA et al, because it would have been obvious to substitute one known electron transfer mediator for another.

Furthermore, the use of either of the phenothiazine or phenoxazine mediators facilitates electrochemical oxidation at lower potentials than standard mediators, making it more beneficial in regeneration, as stated in column 17, lines 2-17 of BLOCZYNSKI et al.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

krs
7/30/2009